DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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JUL - 7 1999

Warning Letter

Via Federal Express

Mr. Thad Morris
CEO
Worldwide Medical Corporation
199 Technology Drive
Suite 150
Irvine, California 92618

Dear Mr. Morris:

We are writing to you because the Food and Drug Administration has received information that revealed a serious regulatory problem with the product labeled as First Check, which is manufactured and marketed by your firm.

The device is marketed in three formats: Panel 1 detects the presence of marijuana; Panel 2 detects the presence of cocaine and marijuana; and Panel 4 detects the presence of marijuana, cocaine, opiates and methamphetamines.

The package insert for the marijuana assay (Panel 1) states the following: "First Check Marijuana provides immediate information about the use of marijuana. It is not for legal, law enforcement, or medical purposes. For diagnosis and treatment, consult with a health care or substance abuse professional."

The package inserts for the other drug assays (Panel 2 and 4) state the following: "First Check Home Drug Tests - provide immediate information about the use of drugs. They are not for legal, law enforcement, or medical purposes."

In spite of the disclaimers, the product is considered to be a medical device under section 201(h) of the Federal Food, Drug, and Cosmetic Act. Under this Act, manufacturers of medical devices are required to obtain marketing clearance for their products from FDA before they may offer them for sale.

Our records do not show that you obtained marketing clearance before you began offering your product for sale. You can obtain FDA's requirements on the type of information to be included in a premarket notification for this device by contacting Jean Cooper, DVM, Chief, Clinical Chemistry and Toxicology Branch, Division of Clinical Laboratory Devices, at 301-594-1243, extension 153. Please note that a guidance document outlining data and labeling requirements for these devices can be found at http://www.fda.gov/cdrh/ode/odecl272.html.

Because you do not have marketing clearance from FDA, marketing your product is a violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your product is adulterated under the Act because you did not submit information that shows your device is safe and effective. Your product is misbranded under the Act because you did not submit information that shows your device is substantially equivalent to other devices that are legally marketed.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date that you receive this letter what steps you are taking to correct the problem involving the sale of unapproved/uncleared products by your company. We also ask that you explain how you plan to prevent this from happening again and what you will do about unapproved/uncleared products currently in retail outlets. If you need more time, please let us know why and when you expect to complete your correction. Please direct your response to Betty Collins, Chief, In Vitro Diagnostic Devices Branch, Center for Devices and Radiological Health, 2094 Gaither Road, HFZ-321, Rockville, Maryland 20850.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance for your device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or the Internet at http://www.fda.gov.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of the letter, please feel free to contact Betty Collins or Broden Staples at (301) 594-4588.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health